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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,744	08/20/2003	Steve T. Lin	19870.052201	9151

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/645,744	LIN ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-111* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-11,13,16,18,19,24,27-29,31-37,39,43,45,46,51 and 104-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4,12,14,15,17,20-23,25,26,30,38,40-42,44,47-50,52-103 and 108-111.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks and IDS, all filed 2/07/08. Claims 1, 13, 24, 27, 39, 51, 104 and 106 are amended. Claims 1-111 are pending.

The request for reconsideration is persuasive because the claims were amended on 3/27/2007 and it appears that the claims that were considered are the original claims filed 8/20/03.

Election/Restrictions

1. Applicant elected claims 1, 2, 4-11, 13, 16, 18, 19, 24, 27, 28, 30-37, 39, 43, 45, 46, 51 and 104-107 in the reply filed on 3/26/07 is as reading on Group I of the restriction requirement. At the same time, claims 1, 27, 104 and 106 were amended to recite that the osteotherapeutic material is demineralized bone matrix. It is also noted that applicant withdrew claims 3 and 29 that recite demineralized bone matrix. It would appear that claims 4 and 30 should have been withdrawn instead. However this issue was not raised in the previous office action.

Furthermore, applicant was required in the restriction/election requirement of 9/27/06 to elect i)one specific disclosed water-soluble block or one specific disclosed carbonate or one specific disclosed ester biodegradable block or one specific disclosed polymerizable group; ii) one specific disclosed osteotherapeutic material; iii) one specific disclosed initiator; iv) one specific disclosed macromer-macromer functional group or one specific disclosed reactive functional group; v) one specific disclosed macromer. Applicant did not specifically elect a water soluble polymer, osteotherapeutic material, initiator, functional group or macromer. But since claims 1, 27, 104 and 106 recite demineralized bone matrix, and the components of the

macromer carrier, and applicant's argument regarding demineralized bone matrix is indicative of the election of demineralized bone matrix.

On the basis of the demineralized bone matrix, claims 4 and 30 are withdrawn from consideration and claims 3 and 29 are included with the examined claims.

Thus, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)), claims 4, 12, 14, 15, 17, 20-23, 25, 26, 30, 38, 40-42, 44, 47-50, 52-103 and 108-111 are withdrawn without prejudice. Claims 1, 2, 3, 5-11, 13, 16, 18, 19, 24, 27, 28, 29, 31-37, 39, 43, 45, 46, 51 and 104-107.

Information Disclosure Statement

Applicant states that the information disclosure statement lists "a number of patents/applications including subject matter directed to carrier of the type currently claimed." However, applicant did not point to specific references that include the subject matter directed to the carrier currently claimed. The response to the last office action did not address this issue.

Previous rejections that re not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 3, 5-11, 13, 16, 18, 19, 24, 27, 28, 29, 31-37, 39, 43, 45, 46, 51 and 104-107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Amended claims 1, 27, 104 and 106 recite the "weight of the demineralized bone matrix ranges from about 53% to about 87% of a combined weight of the demineralized bone matrix plus the macromer." Applicant has not provided the section of the specification that supports this limitation and the as filed specification does not provide support for this limitation such that the limitation is not envisioned by the as filed specification.

Applicant may overcome the new matter rejection by removing the new matter from the claims

5. Claims 3 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1 and 27 limit the osteotherapeutic material to demineralized bone matrix. It is thus unclear how claims 3 and 29 would further limit the osteotherapeutic material to cortical cancellous bone chips.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 5-11, 13, 16, 18, 19, 24, 27-29 31-37, 39, 43, 45, 46, 51 and 104-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarrett et al. (WO 98/12243) in view of Helm et al. ("Utilization of type I collagen gel, demineralized bone matrix, and bone morphogenetic protein-2 to enhance autologous bone lumber spinal fusion," in J Neurosurg 86: 93-100, 1997) or Bolander et al. ("The use of Demineralized Bone Matrix in the Repair of Segmental Defects," in the Journal of Bone and Joint Surgery, 1986, 1264-1274).

Jarret teaches macromer carrier composition (abstract), the macromers are block copolymers including water soluble block, at least one biodegradable block and at least one polymerizable group (page 2, line 28 to page 3 line 1); at least one of the biodegradable block comprises carbonate or dioxanone and the macromer can also contain other degradable linkages or groups in addition to the carbonate or dioxanone (page 3, lines 1-4) with poly(hydroxyl acid) such as lactic acid and glycolic acid, polycaprolactones, polyorthoesters, polyanhydrides (page 3, lines 9-13; page 15, lines 4-23) as the other degradable linkages; such other linkage; the carbonate may come from trimethylene carbonate (Figures 1 and 3; page 15, lines 25-28); the structure of the macromer meets the structure of the claimed macromer in claims 1, 24, 27, 51, 104 and 106. The carrier composition is used as a drug delivery device for the delivery of therapeutic agents (page 1, lines 4 and 5; page 27, line 2 to page 28 line 13), used in sealing leaks in tissue (page 24, lines 9-29) and in orthopedic surgery, it can be used as bone repair (page 25, lines 11 and 12). The carrier composition may also contain free radical photoinitiator such as eosin or eosin Y (page 26, lines 28-31) meeting claims 10, 11, 13, 36, 37 and 39. The carrier composition is aqueous (page 26, line 25) meeting claims 2, 28, 105 and 107. The carrier composition is applicable for human use (page 14, line 18; page 33, line 27) meeting the claims requiring vertebrates and humans, claims 5, 8, 9, 34 and 35. The presence of hyaluronic acid, dextran and heparin (page 14, lines 9-11) meets the limitation of additive in claims 18 and 19. See also page 9, line 22 to page 17, line 30. Regarding, the amount of demineralized bone matrix, a person of ordinary skill in the art would have good reason to use appropriate amount of demineralized bone matrix that would be effective for bone repair.

While Jarret discloses the carrier composition of the claimed invention, and while Jarret discloses that the carrier composition is a drug delivery device and specifically mentions the use of the composition for repair of bone, the carrier composition of Jarret does not contain demineralized bone matrix material. However, it is known in the art that demineralized bone matrix is used for bone repair according to Helm and Bolander. Therefore, taking the general teachings of the prior art, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that inclusion of demineralized bone matrix in the composition of Jarret would effectively repair bone.

Response to Arguments

10. Applicant's arguments filed 2/07/08 have been fully considered but they are not persuasive.

11. Applicant argues that the carrier composition of Jarret does not contain demineralized and that the combination of Jarret and Rodgers does not teach the claimed invention. Regarding, Jarret, the examiner notes that the carrier composition does not contain demineralized bone matrix, hence the rejection is made under 35 USC 103 and not under 35 USC 102. Secondly, a new rejection is made using Helm and Bolander as secondary references that teach bone repair using demineralized bone matrix.

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618